## FEB 27 mm and the and

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

n re application of:	)
	)
Joseph V. BOYKIN, JR.	) Group Art No. TBA
	)
Serial No.: 10/716,657	) Examiner: TBA
,	)
Filed: November 20, 2003	) Docket No: 004629.0002

For:

PREDICTING OUTCOME OF HYPERBARIC OXYGEN THERAPY TREATMENT

WITH NITRIC OXIDE BIOAVAILABILITY

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §1.97, Applicant submits herewith Form PTO-1449, identifying information for consideration by the Examiner. A copy of the items of information is enclosed.

Applicant does not waive any rights to take appropriate action to establish patentability over the listed documents should they be applied as a reference against the claims of the present application.

Consideration of the cited information and making the same of record in the prosecution of the above-noted application are respectfully requested. Should the Patent and Trademark Office determine that a fee is required, please charge our Deposit Account No. 19-0733.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: 入2スト

Susan A. Wolffe

Reg. No. 33,568

1001 G Street, N.W.

Washington, D.C. 20001-4597

(202) 824-3000

Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitut	te for form 144				of information unless it contains a valid OMB of Complete if Known	$\overline{}$	0 6
				Application Number	ТВА	$\neg \vdash$	,
INFO	DRMATI	ON DIS	CLOSURE	Filing Date	November 20, 2003	B	FEB 2 7 2004
STA	TEMEN	T BY A	PPLICANT	First Named Inventor	Joseph V. Boykin, Jr.	B	1 .
				Art Unit	TBA	- E	1. 19
	(use as ma	ny sheets as	necessary)	Examiner Name	TBA		BADEMARIA!
Sheet	1	of	5	Attorney Docket Number	004629.00024		7

			U.S. PATENT [	OCUMENTS	
Examiner	Cito	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant
Initials *	Cite No. <sup>1</sup>	Number - Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear
		US-5,912,114	06-15-1999	Hutchinson et al.	
		US- 6,312,663	11-06-2001	Boykin, Jr.	
		US- 6,334,181	02-05-2002	Boykin, Jr.	
		US- 6,436,366	08-20-2002	Boykin, Jr.	
		US-			
		US-			
		US-	,		
		US-			
		US-			
		US-			
	]	US-			
		US-			***
		US-			

	-	FOREIGN PA	TENT DOCU	MENTS		
Cuminas	Cit-	Foreign Patent Document	B. L.C	Name of Patentee or	Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date - MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup> ·
	ļ					
		-				

		_
Examiner Signature	Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to

place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b(05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Production Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO Complete if Known **Application Number** 10/716,657 INFORMATION DISCLOSURE Filing Date November 20, 2003 STATEMENT BY APPLICANT First Named Inventor Joseph V. Boykin, Jr. Group Art Unit **TBA** (use as many sheets as necessary) **Examiner Name TBA** of | 5 Sheet 004629.00024 Attorney Docket Number

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Peter LIBBY, "Atherosclerosis: The New View" Scientific American, May 2002, pp. 47-55.	
"		Joseph V. BOYKIN, JR., "Letter to the Editor", Wound Repair and Regeneration, International Journal of Tissue Repair and Regeneration, September-October 2001, pp. 391-392.	
,		E.B. JUDE, et al., "The role of nitric oxide synthase isoforms and arginase in the pathogenesis of diabetic foot ulcers: possible modulatory effects by transforming growth factor beta 1", Diabetologia (1999), Vol. 42, pp. 748-757.	
,		Stephen THOM, et al., "Stimulation of perivascular nitric oxide synthesis by oxygen", Am J Physiol Heart Circ Physiol; www.ajpheart.org, December 27, 2002, pp. H1230-H1239.	
		Joseph V. BOYKIN, JR., "The Nitric Oxide Connection: Hyperbaric Oxygen Therapy, Becaplermin, and Diabetic Ulcer Management", Journal for Prevention and Healing Advances in Wound Care; www.woundcarenet.com, July/August 2000.	
		NAVAS, et al., "Inactivation of Factor C by Dimethyl Sulfoxide Inhibits Coagulation of the Carcinoscorpius Amoebocyte Lysate", Biochemistry International, Vol. 21, No. 5, August 1990, pp. 805-813.	
		Joseph V. BOYKIN, JR., "Hyperbaric Oxygen Therapy: A Physiological Approach to Selected Problem Wound Healing", WOUNDS; , Vol. 8, No. 6, November/December 1996, pp. 183-198.	
		Eman EL-SALAHY, et al., "New scope in angiogenesis: Role of vascular endothelial growth factor (VEGF), NO, lipid peroxidation, and vitamin E in the pathophysiology of pre-eclampsia among Egyption females", Clinical Biochemistry 34, 2001, pp. 323-329.	
		Sharon O'BYRNE, et al., "Nitric Oxide Synthesis and Isoprostane Production in Subjects With Type 1 Diabetes and Normal Urinary Albumin Excretion", Diabetes, Vol. 49, May 2000, pp. 857-862.	
		Jeffrey BULGRIN, et al., "Nitric Oxide Synthesis is Suppressed in Steroid-Impaired and Diabetic Wounds", WOUNDS: A Compendium of Clinical Research and Practice, Vol. 7, No. 2, March/April 1995, pp. 48-57	
		E.P. COHEN, et al., "The Role of Nitric Oxide in Radiation Nephropathy", Archives of Physiology and Biochemistry, Vol. 104, No. 2, 1996, pp. 200-206.	

$\overline{}$		
Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Subs	titute for form 144	9A/PTO	. <del>_</del>		Complete if Known
1817		ON DIG	CLOCUBE	Application Number	10/716,657
			CLOSURE	Filing Date	November 20, 2003
SI	AIEMEN	IBYA	PPLICANT	First Named Inventor	Joseph V. Boykin, Jr.
				Group Art Unit	ТВА
	(use as ma	ny sheets as	necessary)	Examiner Name	TBA
Shee	et 3	of	5	Attorney Docket Number	004629.00024

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Michael SCHAFFER, et al., "Nitric Oxide Regulates Wound Healing", Journal of Surgical Research 63, 1996, pp. 237-240.	
		G. A. C. MURRELL, et al., "Modulation of tendon healing by nitric oxide", Inflammation Research 46, 1997, pp. 19-27.	
		Michael SCHAFFER, et al., "Nitric Oxide Metabolism in Wounds", Journal of Surgical Research 71, 1997, pp. 25-31.	
		Stephen WILLIAMS, et al., "Impaired Nitric Oxide-Mediated Vasodilation in Patients With Non-Insulin-Dependent Diabetes Mellitus", JACC, Vol. 27, No. 3, March 1996, pp. 567-574.	
		Yasuhiro NOZAKI, et al., "Nitric oxide as an inflammatory mediator of radiation pneumonitis in rats", The American Physiological Society, 1997, pp. L651-L658.	
		Marianna HUSZKA, et al., "The Association of Reduced Endothelium Derived Relaxing Factor-No Production With Endothelial Damage and Increased in Vivo Platelet Activation in Patients with Diabetes Mellitus", Thrombosis Research, Vol. 36, No. 2, 1997, pp. 173-180.	
		Frank THORNTON, et al., "Healing in the Gastrointestinal Tract", Wound Healing, Vol. 77, No. 3, June 1977, pp. 549-573.	
		Anders ULLAND, et al., "Altered Wound Arginine Metabolism by Corticosterone and Teinoic Acid", Journal of Surgical Research 70, 1997, pp. 84-88.	
		Michael SCHAFFER, et al., "Diabetes-impaired healing and reduced wound nitric oxide synthesis: A possible pathophysiologic correlation", Surgery, Vol. 121, 1997, pp. 513-519.	
		Maria CATALANO, et al., "Basal nitric oxide production is not reduced in patients with noninsulin-dependent diabetes mellitus", Vascular Medicine, Vol. 2, 1997, pp. 302-305.	
		Michael SCHAFFER, et al., "Abstract [Nitric oxide is decreased in diabetic wound healing]", Langebecks Arch Chir Suppl. Kongressbd, Vol. 114, 1997, pp. 519-521.	

Examiner	Date	
Lxammer	Date	
Signature	Considered	
( Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 04/30/2003. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute	for form 1449A/PTO				Complete if Known
INIEO	FORMATION DISCLOSURE FATEMENT BY APPLICANT	CL OCUDE	Application Number	10/716,657	
				Filing Date	November 20, 2003
STAT	EMENT B	ΥA	PPLICANT	First Named Inventor	Joseph V. Boykin, Jr.
				Group Art Unit	TBA
	(use as many she	ets as	necessary)	Examiner Name	TBA
Sheet	4	of	5	Attorney Docket Number	004629.00024

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
		Liangwen SONG, et al., "The Protective Action of Taurine and L-Arginine in Radiation Pulmonary Fibrosis", Journal of Environmental Pathology, Toxicology and Oncology, Vol. 17, No. 2, 1998, pp. 151-157.	
		D. CLARENCON, et al., "Voltametric measurement of blood nitric oxide in irradiated rats", Int. J. Radiat. Biol., Vol. 75, No. 2, 1999, pp. 201-208.	
		Alexander MINCHENKO, et al., "Endothelin-1, Endothelin Receptors and ecNOS Gene Transcription in Vital Organs During Traumatic Shock in Rats", Endothelium, Vol. 6, No. 4, 1999, pp. 303-314.	
		Michael SCHAFFER, et al., "Lymphocyte function in wound healing and following injury", British Journal of Surgery, Vol. 85, 1998, pp. 444-460.	
	_	Mary BLISS, "Hyperaemia", Journal of Tissue Viability, Vol. 8, No. 4, 1998, pp. 4-13.	
		Chris BAYLIS, et al., "Measurement of nitrite and nitrate levels in plasma and urine - what does this measure tell us about the activity of the endogenous nitric oxide system?", Nephrology & Hypertension, Vol. 5, No. 29, 1998, pp. 59-62.	
		Aristidis VEVES, et al., "Endothelial Dysfunction and the Expression of Endothelial Nitric Oxide Synthetase in Diabetic Neuropathy, Vascular Disease, and Foot Ulceration", Diabetes, Vol. 47, March 1998, pp. 457-463.	
		Tsuneki SUGIHARA, et al., "Preferential Impairment of Nitric Oxide-Mediated Endothelium-Dependent Relaxation in Human Cervical Arteries After Irradiation", American Heart Association, Inc.; www.circulationaha.org, 1999, pp. 635-641.	-
		William DODSON III, et al., "3-Nitrotyrosine Predicts Healing in Chronic Diabetic Foot Wounds Treated with Hyperbaric Oxygen", Clinical Research, Vol. 11, No. 6, November/December 1999, pp. 129-136.	
		David EFRON, et al., "Expression and Function of Inducible Nitric Oxide Synthase During Rat Colon Anastomotic Healing", J. Gastrointest Surg., Vol. 3, 1999, pp. 592-601.	
		Hang Ping SHI, et al., "Supplemental dietary arginine enhances wound healing in normal but not inducible nitric oxide synthase knockout mice", Surgery, Vol. 128, 2000, pp. 374-378.	

	· · · · · · · · · · · · · · · · · · ·		
Examiner		Date	]
		Date	
Signature		Considered	
ga.cc		Considered	J. J.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known			
INIEO	DALATION	DIC	CLOCUDE	Application Number	10/716,657
	_	-	CLOSURE	Filing Date	November 20, 2003
STATEMENT BY APPLICANT				First Named Inventor	Joseph V. Boykin, Jr.
				Group Art Unit	TBA
(use as many sheets as necessary)		Examiner Name	TBA		
Sheet	5	of	5	Attorney Docket Number	004629.00024

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No.1	Include name of the author-(in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2		
		Barry CAMPBELL, et al., "Vascular endothelial growth factor attenuates trauma-induced injury in rats", British Journal of Pharmacology, Vol. 129, 2000, pp. 71-76.			
		Thomas MISKO, et al., "A Fluorometric Assay for the Measurement of Nitrite in Biological Samples", Analytical Biochemistry, Vol. 214, 1993, pp. 11-16.			
	-	Mary GILLIAM, et al., "A spectrophotometric Assay for Nitrate Using NADPH Oxidation by Aspergillus Nitrate Reductase", Analytical Biochemistry, Vol. 212, 1993, pp. 359-365.			
		Jeffrey BULGRIN, et al., "Arginine-free diet suppresses nitric oxide production in wounds", J. Nutr.Biochem, Vol. 4, October 1993, pp. 588-593.			
		Joseph BOYKIN, JR., et al., "Diabetes-Impaired Wound Healing Predicted by Urinary Nitrate Assay: A Preliminary, Retrospective Study", WOUNDS: A Compendium of Clinical Research and Practice, Vol. 11, No. 3, May/June 1999, pp. 62-69.			

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application from to the USPTO. Time will vary depending upon the individual case. Any comments on the agreement of time your requires to complete designation for requiring the burden, should be soon to the Chief. case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.